TCT-405

Rotational Atherectomy Following by Second-generation Drug-eluting Stents Implantation Against Heavily Calcified Coronary Lesions

Munetaka Yamaguchi[1], Hideki Shimomura[1], Yoshihiro Yamada[1], Takashi Kudoh[1], Yoshinori Nakamura[1], Yuji Ogura[1], Takeshi Nagata[1], Naomi Chazono[1], Kenshi Yamanaga[1], Yoshiro Onoue[1], Hisao Ogawa[2]
[1]Department of Cardiovascular Medicine, Fukuoka Tokushukai Medical Center, Fukuoka, Japan; [2]Department of Cardiovascular Medicine, Graduate School of Medical Sciences, Kumamoto University, Kumamoto, Japan

Background: The rate of target lesion revascularization (TLR) against heavily calcified coronary lesions is still high and remaining unresolved problem even in drug-eluting stent (DES) era.The aim of this study was to evaluate the outcome of patients with these lesions undergoing rotational atherectomy (RA) followed by implantation of second-generation DES.
Methods: We performed coronary intervention using Zotarolimus or Everolimus eluting stent against consecutive de-novo 893 lesions/590 patients since May 2009 to October 2010. Angiographical follow-up (mean; 198±88.6 days, range; 164-346 days) was performed in 718 lesions/451 patients. We divided these lesions into 2 groups. One is heavily calcified coronary lesions required RA (HCCL), the other is not heavily calcified lesions without the need of RA (NHCCL). HCCL comprised of 135 lesions, 92 were treated with Zotarolimus-eluting stent (ZES) and 43 were with Everolimus-eluting stent (EES). NHCCL comprised of 583 lesions, 355 were with ZES and 228 were with EES. We compared clinical safety and efficacy between 2 groups.
Results: The total lesion length was longer in HCCL (21.6±19.0 vs. 17.4±6.3 mm, p<0.05), although reference diameter was larger in HCCL (3.06±0.46 vs. 2.78±0.48 mm, p<0.05). The maximum burr size of rotablator per lesion was 1.73±0.15 mm. The ratio of successful stent delivery was 100% in HCCL and 99.8% in NHCCL (p=0.63). Procedural success rate was equivalent in both groups (90.4% vs. 93.7%, p=0.20) and there was no in-hospital major advertise cardiac events (MACE) difference (0% vs. 0.4%, p=0.30). At 6 months, the rate of TLR was 3.7% in HCCL vs. 6.3% in NHCCL (p=0.46), and there were no differences in the ratio of MACE between 2 groups (3.7 % in HCCL vs. 6.7% in NHCCL, p=0.30).

Conclusion: Second-generation DES implantation using RA to facilitate dilatation against heavily calcified lesions appears to be feasible including high rate of procedural success rate and low-incidence of TLR as well as the results in non-heavily calcified lesions.

TCT-406

SYNTAX Score Does Not Add to Clinical Risk Score in a Typical PCI Population

Julian Gunn, Mina Ghobrial, Tushar Raina, Chris Malkin, Anjan Siotia, Allison C Morton
Cardiovascular Science, University of Sheffield, Sheffield, United Kingdom

Background: The patterns of disease and clinical risk profile of patients being treated with percutaneous coronary intervention (PCI) is becoming increasingly complex. There is a strong move towards adopting risk stratification. Several clinical PCI risk scores exist, but generally include little data on the location, severity or complexity of lesions. Conversely, the SYNTAX score, designed to characterise the disease pattern in the SYNTAX study (patients with 3 vessel and left main disease) includes no clinical data. We aimed to investigate the value of combining SYNTAX with a clinical risk score to predict 30day and 1 year mortality after PCI
Methods: We reviewed the clinical and angiographic records of all patients who underwent PCI in 2006 at Sheffield, a regional public cardiothoracic centre (>50% patients having acute coronary syndromes). In prior work we had already constructed a clinical PCI risk score appropriate for our institution (Sheffield Risk Score, SRS), appropriately validated. This, and the SYNTAX score, was calculated for our cohort. Univariate analyses were carried out for each variable with 30 day and 1 year mortality. Logistic regression was used to create risk prediction models, which were assessed for their discrimination and calibration using ROC curves and the Hosmer-Lemeshow test
Results: 1670 PCIs were studied. All relevant clinical variables and the SYNTAX score were strongly associated with mortality at 30 days and 1 year (p<0.001). ROC curve analysis showed no improvement in c-statistics [measuring accuracy of prediction] for the combination of SYNTAX and SRS vs SRS alone for mortality at 30 days (c=0.93 vs 0.91) and 1 year (c=0.83 vs 0.83), despite patients in the highest SYNTAX tertile (score >15) having, as expected, lower survival at 30d (96 vs 99%) and 1y (94 vs 98%) than the lower two tertiles combined (p < 0.001).
Conclusion: The combination of SYNTAX score with a clinical PCI risk score does not result in any significant improvement in the accuracy of predicting survival at 30 days or 1 year in an all-comers population undergoing PCI.

Heart Disease in Women

(Abstract nos 416 - 424)

TCT-416

Female Patients with Acute Coronary Syndrome: Two Years Clinical Outcomes

Philip Urban[1], Osmund Bertel[2], Olivier Darremont[3], Nicos Spyrou[4], Vincenzo Filippone[5], Francesco Romea[6], Do Quan Huan[7], Ahmet Tastan[8], Andre Georges Vuilliomenet[9], Xu-Ming Zhang[10], Gian Battista Danzi[11]
[1]Hôpital de la Tour, Meyrin, Switzerland; [2]Klinik im Park, Zurich, Switzerland; [3]Clinique Saint Augustin, Bordeaux, France; [4]Royal Birkshire, Reading, United Kingdom; [5]A.O.V. Cervello, Palermo, Italy; [6]Policlinico Universitario Di Tor Vergata, Roma, Italy; [7]Heart institute of HCMC, Ho Chi Minh, Viet Nam; [8]Sifa Hospital, Izmir, Turkey; [9]Kantonsspital Aarau, Aarau, Switzerland; [10]Kiang Wu Hospital, Macau, Macao; [11]Ospedale Maggiore Policlinico, Milano, Italy

Background: The increasing use of coronary stenting has improved the outcome of PCI in several patient cohorts, including female patients. However, more information about the long term outcomes for women treated in the course of acute coronary syndrome (ACS) is needed. We investigated the late clinical outcomes in female patients as compared to males presenting with ACS and treated with a new generation drug eluting stent coated abluminally with Biolimus A9 and biodegradable polymer.
Methods: Among 3067 consecutive patients treated with Nobori DES and enrolled in NOBORI2 study, 372 female and 1268 male patients presented in the course of ACS. Primary endpoint of the study was target lesion failure (TLF), a composite of cardiac death, target vessel related MI and target lesion revascularization (TLR) at 1 year. Data are entered in an electronic database; adverse events are adjudicated by an independent clinical event committee and an independent corelab analyses all angiograms.
Results: Female patients were older, had significantly higher incidence of diabetes and hypertension and presented with more comorbidities compared to males. However, they had less previous revascularizations and history of smoking. Lesion complexity was similar, but more male patients had bifurcation lesions. Number of lesions treated and stents implanted was lower in female patients. Except higher RVD and diameter stenosis post-procedure in male vs female, the majority of QCA assessed parameters were not significantly different. At 2 year follow-up TLF was slightly higher in female patients (7.3% vs 5.7%; p=NS). In female group 12 patients died of a cardiac cause (3.2%), 13 (3.5%) had an MI and 17 (4.6%) a TLR. In male group, 25 patients (2.0%) died, 32 (2.5%) had an MI and 41 (3.2%) a TLR. Stent thrombosis was also slightly more frequently reported in female patients (1.0% male vs 1.9% female patients; p=NS).
Conclusion: Despite higher age, more frequent presence of risk factors and co-morbidities in female patients, clinical outcomes two years after treatment for ACS were comparably excellent in both genders.

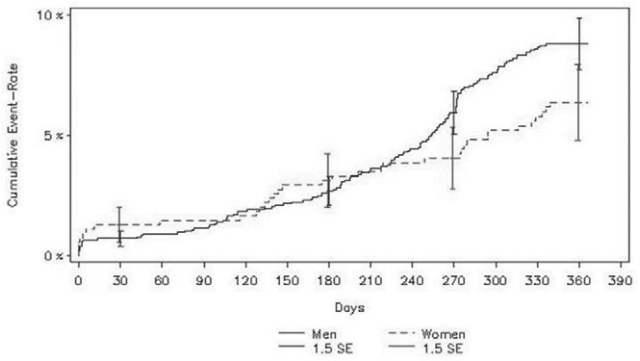
TCT-417

Gender-specific outcomes after paclitaxel-eluting stent implantation in Japanese patients with coronary artery disease: a sub-analysis of Japan TAXUS Express2 post-marketing survey

Hiroyuki Okura[1], Jun-ichi Kotani[2], Ken Kozuma[3], Masato Nakamura[4]
[1]Cardiology, Kawasaki Medical School, Kurashiki, Japan; [2]National Cerebral and Cardiovascular Center, Osaka, Japan; [3]Teikyo University Hospital, Tokyo, Japan; [4]Toho University Ohashi Medical Center, Tokyo, Japan

Background: Previous data from randomized trials and registries demonstrated that paclitaxel-eluting stent (PES) was as safe and effective in both men and women, except for a slightly higher revascularization rate in women among the highest risk population. We performed a sub-analysis of Japan TAXUS Express2 post-marketing survey registry to assess the influence of gender on clinical outcomes after implantation of PES in Japanese patients with coronary artery disease.
Methods: We analyzed 2132 PES-treated Japanese patients (women, n=551) from this real world registry. Study patients were stratified by gender to compare 1 year clinical outcome.
Results: PES-treated women were older (71.9±8.4 vs. 67.0±9.6, p<0.0001) and more likely to be insulin treated diabetes and hypertension. By contrast, PES-treated men were more likely to be smoker, had a previous history of myocardial infarction, and lower ejection fraction. Angiographically, women had significantly smaller reference vessel size (2.46±0.53 vs. 2.59±0.60 mm, p<0.0001). At 1 year follow-up, cardiac death, myocardial infarction and stent thrombosis (ARC definite or probable) were similar between men and women. Target lesion revascularization rate was significantly lower in women than in men (4.2 % vs. 6.5 %, p<0.05). Major adverse cardiac event showed a trend toward lower in women than in men (6.4% vs. 8.8 %, P=0.08).

POSTERS



Conclusion: Despite higher risk profile, Japanese women treated with PES tended to have better clinical outcome than PES-treated men at 1 year.

TCT-418

Bivalirudin Use During Percutaneous Coronary Intervention Improves Clinical and Economic Outcomes in Diabetic Women

Erin M Galbraith[1], Roxana Mehran[4], Chandan Devireddy[1], Henry A Liberman[1], Steven V Manoukian[3], Michele D Voeltz[2]
[1]Emory University, Atlanta, GA; [2]Henry Ford Hospital, Detroit, MI; [3]Sarah Cannon Research Institute and Hospital Corporation of America, Nashville, TN; [4]Mount Sinai Medical Center, New York, NY

Background: Bivalirudin is associated with superior safety and economic outcomes with similar efficacy over heparin plus a glycoprotein IIb/IIIa inhibitor (GPI) in percutaneous intervention (PCI). While gender and diabetes are significant drivers of clinical and economic outcomes, it is unclear if bivalirudin maintains its advantages over heparin plus GPI in an unselected group of these high-risk patients.
Methods: Using the Premier Perspective Database, one of the largest administrative US databases of hospital clinical and economic outcomes, female patients with diabetes who had undergone PCI between 2004 and 2010 were identified. Primary endpoints of in-hospital mortality, clinically apparent bleeding, post-PCI length of stay, and hospitalization costs were compared between patients treated with bivalirudin versus heparin plus GPI. Data were unadjusted and propensity score matched.
Results: Data from 61,791 diabetic women was examined in the unadjusted population. Women over 70 years of age and those pre-treated with clopidogrel were more likely to receive bivalirudin (61% and 64%, respectively; p<0.03); whereas those with STEMI or shock were more likely to be treated with heparin plus GPI (81% and 78% respectively; p<0.01). In-hospital mortality and all bleeding parameters were lower in the bivalirudin group. In contrast, post-PCI length of stay and total adjusted hospital costs were significantly greater in the heparin group. When a propensity score matching method was used to minimize baseline differences between comparison groups, all clinical and economic outcomes remained significantly lower in the bivalirudin-treated female diabetics, table 1.

Table 1	All Available Diabetic Female Patients			Propensity Matched 1:1 Population (All patients)		
Outcome	BIV Alone (N=34767)	HEP+GPI (N=27024)	p-value	BIV Alone (N=20011)	HEP+GPI (N=20011)	p-value
Clinically apparent bleeding (%)	5.3	9.6	<0.001	5.5	8.6	<0.001
Clinically apparent bleeding requiring transfusion (%)	1.5	2.9	<0.001	1.5	2.4	<0.001
Any Transfusion (%)	4.7	8.7	<0.001	5.0	7.3	<0.001
In-hospital Mortality (%)	0.7	2.3	<0.001	0.9	1.5	<0.001
Post-PCI Length of Stay in days (MEAN ± SD)	1.3 ± 3.2	2.3 ± 4.3	<0.001	1.4 ± 3.3	1.9 ± 3.7	<0.001
Adjusted Cost of Hospitalization in US dollars (MEAN ± SD)	16757 ± 13594	19613 ± 15641	<0.001	17188 ± 14161	18352 ± 14209	<0.001

"BIV" = Bivalirudin

"HEP + GPI" = Heparin plus glycoprotein IIb/IIIa inhibitor

"PCI" = percutaneous intervention

"US" = United States

Conclusion: In this large population of high-risk patients, real-world bivalirudin use in diabetic women undergoing PCI is associated with lower rates of in-hospital mortality, bleeding, transfusion, post-PCI length of stay, and lower hospitalization costs compared with the use of heparin plus GPI in unadjusted and propensity score matched populations.

TCT-419

Outcomes of Women after Acute Myocardial Infarction: Results from the HORIZONS-AMI Study

Jennifer Yu[1], Roxana Mehran[1, 2], Liliana Grinfeld[3], Ke Xu[2], Martin Fahy[2], Eugenia Nikolsky[4], Rebecca Pinnelas[5], Avery E Clark[6], Bruce R Brodie[7], Martin Mockel[8], Bernard Witzenbichler[8], Ran Kornowski[9], Dariusz Dudek[10], Alexandra J Lansky[11, 2], George Dangas[1, 2], Gregg W Stone[2, 12]
[1]Cardiovascular Research, Mount Sinai Medical Center, New York, NY; [2]Cardiovascular Research Foundation, New York, NY; [3]Hospital Italiano, Buenos Aires, Argentina; [4]Rambam Medical Center, Haifa, Israel; [5]New Jersey Medical School, Newark, NJ; [6]Middlebury College, Middlebury, VT; [7]LeBauer Cardiovascular Research Foundation, Greensboro, CT; [8]Charite Campus Benjamin Franklin, Berlin, Germany; [9]Rabin Medical Center, Tel-Aviv, Israel; [10]Jagiellonian University, Krakow, Poland; [11]Yale University School of Medicine, New Haven, CT; [12]Columbia University Medical Center, New York, NY

Background: The impact of gender on the long-term (greater than 1 year) outcomes of patients with acute myocardial infarction who have undergone primary PCI is not well established.
Methods: We examined 3 year outcomes from the large-scale, randomized HORIZONS-AMI trial according to sex. We used Cox proportional-hazards methods with stepwise selection using entry and exit criteria of p <0.1 to determine the independent predictors of MACE, major bleeding and death. Candidate variables tested were sex; age; diabetes; hypertension; history of smoking; prior MI; prior PCI; prior CABG; Killip class >1; baseline anemia; creatinine; and symptom onset to balloon time.
Results: Compared with men, women were significantly older and had higher prevalence of hypertension and hyperlipidemia (all p<0.05). In contrast, women were less likely to have a prior history of MI, PCI, CABG and were less likely to be smokers (all p<0.05). Women were less likely to undergo primary PCI in favor of medical management (p<0.05). They had longer symptom to balloon time (p=0.007). Female gender was associated with increased MACE, death and major bleeding at 3 year follow-up (Table). After multivariable analysis female gender remained an independent predictor of major bleeding, but not of MACE or death.

Patient Outcomes at 3 years

	Female (N=842)	Male (N=2760)	P value
MACE	24.0%	21.2%	0.046
Major Bleeding (non-CABG related)	13.8%	7.2%	<0.0001
Death	8.2%	6.4%	0.06
Reinfarction	7.1%	7.2%	0.91
Stroke	2.1%	1.8%	0.47
Ischemic TVR	14.5%	12.8%	0.14
Definite or Probable ST	5.3%	5.0%	0.71

MACE = Major adverse cardiovascular events, composite of death, reinfarction, stroke, ischemic TVR; CABG= coronary artery bypass graft; TVR = target vessel revascularization; ST = stent thrombosis

Conclusion: In the HORIZONS-AMI trial, women had a more unfavorable cardiovascular risk profile compared with men. Female gender was an independent predictor of long-term major bleeding (HR[95%CI] = 1.77 [1.38, 2.27], P<0.0001, but not of death (0.92 [0.68, 1.26], P=0.62) or overall MACE (1.17 [0.98, 1.40], P=0.08).

TCT-420

Predictors of Major Adverse Events in Female Patients with Acute Myocardial Infarction undergoing Primary PCI: Three Year Results from the HORIZONS-AMI Study

Jennifer Yu[1], Roxana Mehran[1, 2], Ke Xu[2], Avery E Clark[3], Rebecca Pinnelas[4], Bernhard Witzenbichler[5], Ran Kornowski[6], Giulio Gaugliumi[7], Eugenia Nikolsky[8], Bruce R Brodie[9], Alexandra J Lansky[10], George Dangas[1, 2], Gregg W Stone[2, 11]
[1]Mount Sinai Medical Center, New York, NY; [2]Cardiovascular Research Foundation, New York, NY; [3]Middlebury College, Middlebury, VT; [4]New Jersey Medical School, Newark, NJ; [5]Charite Campus Benjamin Franklin, Berlin, Germany; [6]Rabin Medical Center, Tel-Aviv, Israel; [7]Ospedali Riuniti de Bergamo, Bergamo, Italy; [8]Rambam Medical Center, Haifa, Israel; [9]LeBauer Cardiovascular Research Foundation, Greensboro, CT; [10]Yale University School of Medicine, New Haven, CT; [11]Columbia University Medical Center, New York, NY

Background: Although female patients are at high risk for unfavorable outcomes after STEMI, the independent predictors of major adverse cardiac events (MACE) at long term follow up have not been described.
Methods: We examined 3-year outcomes of female patients (n=842) from the large-scale, prospective, multicenter, HORIZONS-AMI trial where patients were randomized to receive heparin plus glycoprotein IIb/IIIa inhibitor or bivalirudin, and paclitaxel eluting stents or bare metal stents in a 2 by 2 factorial design. After the performance of univariate analysis, we used Cox proportional-hazards methods with stepwise selection using entry and exit criteria of p<0.1 to determine the independent predictors of MACE, mortality and reinfarction. Candidate variables tested were age, hypertension, diabetes, history of smoking, peripheral vascular disease, family history of premature CAD, prior MI, prior PCI, prior CABG, Killip Class on presentation, and door to balloon time.
Results: The median age was 66 (95% CI 57.1-75.3), 51% were smokers, 19% had diabetes, 3.3% had chronic renal insufficiency. The 3- year rates of mortality, reinfarction and MACE were 8.2%, 7.1% and 24% respectively. The table summarizes